

REMARKS

1. STATUS OF THE CLAIMS

Claims 136, 144-152, 154, 155, 157-159, 162-164, 167-176 are pending, of which Claims 144-152, 154, 155, 157-159, and 162-164 were previously withdrawn. Thus, Claims 136, 167-176 are currently under examination.¹

Claim 136 is currently amended to clarify the carboxylated glycan is the same, by reciting "said" when in reference to the "carboxylated glycan." Claim 136 is currently also amended for further clarity to recite that the carboxylated glycan of step A) i) is "purified." Claim 136 is further amended by replacing "glycans" with "glycan" to provide antecedent basis.

Claims 167-169 are currently canceled.

Claim cancellations and amendments were made to describe particular embodiments of the invention, notwithstanding Applicants' belief that the cancelled and un-amended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the un-amended (or similar) claims in another application, but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).²

2. RESTRICTION MAILED ON JANUARY 21, 2010

Applicants note, with appreciation, that their prior grounds for traversal of the January 21, 2010 Restriction Requirement were "found to be persuasive and the requirement for restriction mailed on January 21, 2010 is withdrawn. Claims 167-169 are therefore included with the claims under examination."³

¹ Office Action, page 3, item #3.

² 65 Fed. Reg. 54603 (September 8, 2000).

³ Office Action, page 3, 1st paragraph.

3. **REJECTION OF CLAIMS 136 and 167-176 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH (DEFINITENESS)**

Claims 136 and 167-176 were rejected under 35 U.S.C. § 112, second paragraph,⁴ for alleged indefiniteness of the term “carboxylated glycan” on the grounds that it is unclear whether the two carboxylated glycans are the same or different.”⁵

This rejection is moot with respect to Claims 167-169 that are currently canceled.

Claim 136 is currently amended to clarify the carboxylated glycan is the same, by reciting “said” when in reference to the “carboxylated glycan.” Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 136 and 167-176 under 35 U.S.C. § 112, second paragraph.

4. **REJECTION OF CLAIMS 167-169 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)**

The Examiner rejected Claims 167-169 under 35 U.S.C. § 112, first paragraph, for alleged non-enablement,⁶ on the basis that a biological deposit is required to practice the claimed invention that recites the monoclonal antibodies mAbEE4.1, mAbGB3.1, mAbB2.6, and mAbEH2.⁷ This rejection is moot in view of the current cancellation of Claims 167-169.

5. **REJECTION OF CLAIMS 136 AND 170-176 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)**

The Examiner rejected Claims 136 and 170-176 under 35 U.S.C. § 112, first paragraph, for alleged non-enablement.⁸ Applicants respectfully disagree.

The Examiner **admitted** that the Specification is “. . . enabling for identifying a test agent which reduces binding to specific carboxylated glycans . . .”⁹ and that “the disclosure provides guidance for the identification of some agents which reduce inflammation related to the binding of the proteins annexin I, S100A8/A9 and amphoterin . . .”¹⁰

⁴ Office Action, page 3, item #5.

⁵ Office Action, page 3, item #6.

⁶ Office Action page 4, item #8.

⁷ Office Action, page 4, item #9.

⁸ Office Action page 6, item #14.

⁹ *Id.*

¹⁰ Office Action, page 8, item #16; and page 14, item #29.

Nonetheless, the Examiner advanced the following arguments in support of alleged lack of enablement.

“The identification of an agent that reduces inflammation in vitro may not adequately **predict** the effect of the agent when used in a patent in vivo. One of ordinary skill in the art would conclude that the agent would further need to be **assessed** for its ability to reduce inflammation in a tissue, requiring further and undue experimentation,”¹¹ and

“... one of ordinary skill in the art would further be unable to **predict** whether the method would work as claimed (to enable one to detect a reduction I inflammation) with a reasonable expectation of success because one would have **no prior knowledge** whether the test agent would result in reducing inflammation.”¹²

However, the Examiner’s arguments misconstrue the proper test of enablement. The test of enablement is **not**, as the Examiner asserts, whether the artisan can “**predict**” or have “**prior knowledge**” of whether the claimed method “**would work**.” Rather, the test of enablement is:

“whether one skilled in the art could make or use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation.”¹³

“... the key word is ‘undue’ not ‘experimentation.’”¹⁴

Importantly, the enclosed Declaration by Dr. Geetha Srikrishna avers that the “Specification teaches methods for using an art-accepted in vivo animal model of inflammation for screening, using routine experimentation.” The enclosed Declaration by Dr. Geetha

¹¹ (Emphasis added) Office Action, paragraph bridging pages 8-9.

¹² (Emphasis added) *Id.*

¹³ MPEP 2164.01, citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988); *In re Stephens*, 529 F.2d 1343, 188 USPQ 659 (CCPA 1976).

¹⁴ *In re Wands*, 8 USPQ2d 1404, citing *In re Angstadt*, 537 F.2d at 504, 190 USPQ at 219.

Srikrishna is **factually supported** by Srikrishna *et al.*¹⁵ which is **prior art**, since it was published in the January 1, 2001 issue of The Journal of Immunology, which is prior to the December 28, 2001 priority date of the instant application. The enclosed Declaration by Dr. Geetha Srikrishna concludes that the teachings of the Specification and/or the prior art may be applied by one of ordinary skill in the art "**using routine experimentation**" to screen test agents for their effect on inflammation in vivo.

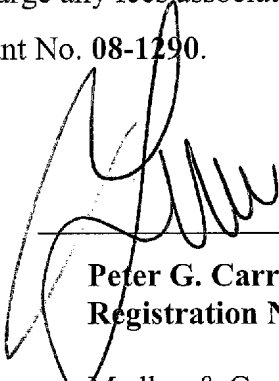
In view of the above, independent Claim 136 (and dependent Claims 170-176) are enabled. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 136 and 170-176 under 35 U.S.C. § 112, first paragraph.

6. **REJECTION OF CLAIMS 167-169 UNDER 35 U.S.C. § 103(a) OVER VARKI *et al.*, SCHMIDT *et al.* AND HODGES *et al.***

The Examiner rejected Claims 167-169 under 35 U.S.C. § 103(a) for alleged obviousness over Varki *et al.* (U.S. Patent No. 5,544,978; cited in prior action) in view of Hodges *et al.* (U.S. Patent No. 5,738,996; cited in prior action).¹⁶ This rejection is moot in view of the cancellation of the current cancellation of Claims 167-169.

The Commissioner is authorized to charge any fees associated with this communication, or credit any overpayments, to Deposit Account No. **08-1290**.

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¹⁵ Srikrishna *et al.*, "A novel anionic modification of N-Glycans on mammalian endothelial cells is recognized by activated neutrophils and modulates acute inflammatory responses," (2001) The Journal of Immunology, January 1, 2001, vol. 166 no. 1 624-632.

¹⁶ Office Action, page 11, item #22.